

Blazer II TM
Steerocath T TM
Steerocath A TM

Boston
Scientific
EP TECHNOLOGIESTM

Cardiac Ablation Catheters

Directions for Use

Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

Boston
Scientific
EP TECHNOLOGIESTM

2710 Orchard Parkway
San Jose, CA 95134 USA

12190-001 AW Ver AA

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Distributed in Europe by:
Boston Scientific
91, Boulevard National
92257 La Garenne Colombes Cedex
France

Made in USA

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

Description:

The EPT-1000 Cardiac Ablation System¹ consists of the EPT-1000 Cardiac Ablation Controller (Controller), Automatic Personality Module (APM), and a steerable cardiac ablation catheter. Detailed Instructions for Use of the EPT-1000 Cardiac Ablation Controller, Automatic Personality Module, footswitch and the EPT Graphics Software are provided in the EPT-1000 Controller Operator's Manual. Information further detailed in this manual specifically addresses the steerable ablation catheters.

The ablation catheter is connected to the EPT-1000 Cardiac Ablation Controller via the Automatic Personality Module (APM). The APM provides for additional connection to standard hospital electrophysiology recorders. The catheter-to-APM connection may be made through the use of the Quick Connect Instrument Cable, which incorporates EPT's proprietary "Quick Connect" connectors, illustrated in Figure 1. The "Quick Connect" configuration allows for rapid disconnection and re-connection of the catheter. An adaptor cable is alternatively available with 2 mm pin connectors, which can connect directly to the Automatic Personality Module as illustrated in Figure 2.

SteeroCath™ and Blazer II™ ablation catheters are illustrated in Figure 3. Usable catheter length from distal-tip electrode to the catheter handle ranges from 60 to 130 cm. Both the SteeroCath-T and Blazer II employ a tip mounted, thermally isolated thermistor for temperature sensing, which enables temperature monitoring at the endocardial surface during ablation. The SteeroCath-A does not feature temperature sensing capabilities. For all ablation catheters, monopolar RF power is delivered between the catheter's distal electrode and a commercially available external Dispersive Indifferent Patch (DIP) Electrode. SteeroCath cardiac ablation catheters have standard torque characteristics; the Blazer II catheter has a relatively higher torque attribute available. The handle and steering mechanism for both the SteeroCath and Blazer II are identical.

Electrode tip configurations, illustrated in Figure 4, are represented by a conventional "straight" tip electrode. Straight tip electrodes are available in sizes ranging from 6Fr / 4 mm to 8Fr / 5mm). The diameter of the catheter shaft ranges from 6 to 7 French. Bipolar or quadripolar catheter configurations are available (one or three ring electrodes, respectively). Ring electrodes are utilized for either electrogram recording and for pacing. The quadripolar design has available ring electrode spacings ranging from 1 mm to 10 mm. The distal tip electrode-to-first ring electrode is a fixed distance of 2.5 mm for all catheter configurations.

Curve options for both catheters include a variety of symmetric and asymmetric ranges of motion. Asymmetric curves, by design, have limited articulation (180° in one direction). Symetric curves can be articulated up to 270° in opposite directions, for a total range of motion of 540°. Distal-end lengths range from the standard length of 6.6 cm to the extended length of 15 cm. For Blazer II, the stiffness characteristic of the distal-end shaft is available as either firm or soft.

The entire range of available dimensions for the EPT Cardiac Ablation Catheters appears in Table B Page 5.

¹ The EPT 1000 series currently includes the model 800T (temperature monitoring) and the 800TC (temperature control) cardiac ablation controllers.

Indications:

The EP Technologies Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia - typically chronic, drug refractory atrial fibrillation.

Contraindications:

The use of the device is contraindicated in patients with active systemic infection.

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

Warnings:

- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- Patients undergoing AV nodal modification or ablation of septal accessory pathways are at risk for inadvertent AV block. It is advisable to use lower initial power in such patients and to monitor anterior conduction closely during RF power delivery.

- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a) have temporary external sources of pacing available during ablation, b) temporarily reprogram the pacing system to minimum output or 000 mode to minimize risk of inappropriate pacing, c) exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and d) perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
- During a transaortic approach, adequate fluoroscopic visualization is necessary to avoid placement of the ablation catheter within the coronary vasculature. Catheter placement and RF power application within the coronary artery has been associated with myocardial infarction and death.
- Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation period for clinical manifestations of infarction.
- The steerable ablation catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The use of catheters or cables with unprotected male pin connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of component with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the vicinity of the *chordae tendinae*. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

Precautions:

- The Blazer II™ catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than 1 1/2 full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall, before resuming rotation of the handle and catheter shaft.
- Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- The sterile packaging and catheter should be inspected prior to use.
- It is recommended not to exceed thirty (30) radiofrequency power applications per catheter.
- The EP Technologies steerable ablation catheter is intended for use with the EPT-1000 Cardiac Ablation Controller and accessories only.
- Do not attempt to operate the EPT Cardiac Ablation System before thoroughly reading the EPT-1000 Cardiac Ablation Controller Operator's Manual.
- The catheter impedance LED display of the Cardiac Ablation Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation in a fully-equipped electrophysiology laboratory.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.

- The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- Read and follow the dispersive indifferent patch (DIP) electrode manufacturer's instructions for use; the use of DIP electrodes which meet or exceed ANSI/AAMI HF-18 requirements is recommended.
- Placement of the DIP electrode on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
- The Cardiac Ablation Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the ablation procedures are performed.
- Electromagnetic interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Regularly inspect and test re-usable cables and accessories. The instrument cables and adapter cables only may be sterilized up to ten times by ethylene oxide sterilization.
- EP Technologies relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the cardiac ablation procedure.

Adverse Events

The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise noted with an asterisk). A total of 57 adverse events were observed in the 513 procedures performed during the clinical study.

Cardiac/Vascular
 Death
 Cardiac Tamponade, Perforation, Pericardial Effusion
 Cerebral Vascular Accident
 Myocardial Infarction
 Endocarditis
 Pulmonary Edema
 Pulmonary Embolism, Venous Thrombus
 * Puncture Site Hematoma, Ecchymosis (2.1%)
 Aortic Valve Insufficiency/Wall Motion Abnormality
 Arrhythmic
 Permanent Atrioventricular Block
 Ventricular Fibrillation
 * Non-sustained Ventricular Tachycardia (1.6%)
 Conduction System Abnormalities
 * Atrial Fibrillation, Flutter, Tachycardia (2.5%)
 Pacemaker Failure-to-sense

Inspection Prior to Use

Prior to use of the EP Technologies Cardiac Ablation System, the individual components including the EPT-1000 Cardiac Ablation Controller, steerable ablation catheter, Quick Connect Instrument Cable, Automatic Personality Module, and Footswitch should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the steerable ablation catheter.

Equipment Required

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. Ancillary materials required to perform cardiac ablation:

- 1) 8 French hemostatic introducer sheath.
- 2) Dispersive Indifferent Patch (DIP) electrode meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes, such as the Valley Labs Polyhesive Electrode #E7506.

Setting up the System

Please refer to the Operator's Manual for the EPT-1000 Cardiac Ablation Controller. The Operator's Manual describes the steps to follow to connect the system, set ablation parameters, and deliver radiofrequency power.

Carefully read all instructions prior to use. Failure to do so may result in complications.

Attaching the Indifferent Electrode

- 1) Remove the DIP electrode from the packaging and peel off the backing to expose the conductive gel surface. Check to be sure the pad is moist and sticky to the touch before placing it on the patient. A dry electrode will have limited grounding capability.
- 2) Place the DIP electrode on a well-vascularized convex skin surface which is in close proximity to the ablation site. Do not place this electrode on the thigh, since this location is associated with higher impedance (See "Precautions"). Avoid scar tissue, body prominence, adipose tissue, and areas where fluid may pool. Shave, clean, and dry the application site as needed.
- 3) Check to be sure that excellent contact has been achieved over the entire area of the DIP electrode. Burns can result when RF power is delivered to a DIP electrode with poor contact.

Plug the DIP electrode connector into the two-prong socket marked "INDIFFERENT ELECTRODE" on the front panel of the APM. Make sure that the DIP electrode connector is firmly pressed into the socket.

Directions for Use:

The steerable ablation catheter is usually inserted into a vein or artery and is then positioned into the appropriate chamber of the heart under fluoroscopic guidance. A transseptal approach may be used (see "Contraindications" and "Warnings"). Precise placement of the catheter prior to ablation is accompanied by endocardial mapping using the tip and/or ring electrodes. Once appropriate positioning has been achieved, radiofrequency power is delivered via the EPT-1000 Cardiac Ablation Controller resulting in the ablation of the targeted cardiac tissue.

Prior to insertion of the steerable ablation catheter, prepare the entry site according to standard aseptic technique practices.

- 1) Insert the catheter percutaneously into the appropriate artery or vein by the Seldinger technique using an 8 French hemostatic introducer sheath.
- 2) Once inside the vessel, the catheter tip can be deflected as necessary to facilitate advancement into the selected heart chamber. The degree of tip deflection is controlled by the Steering Lever on the catheter handle. If the Steering Lever is pushed forward from its neutral position, the tip will curve proportionately up to a maximum of 270 degrees in one direction depending upon the curve option selected. Pulling the Steering Lever back will cause the tip to deflect in the opposite direction. To prevent overstressing the tip, the Steering Lever movement is limited by the handle design.
- 3) When crossing the aortic valve with the ablation catheter, it is recommended that the catheter tip be deflected to resemble a "pigtail" curve to avoid damage to the valve leaflets.
- 4) The catheter curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation. The adjustable Tension Control Lever may be tightened to retain the tip in the desired curvature or to increase steering resistance. Catheters are shipped with the Tension Control Lever in the "(-)" position, which is the minimum tension adjustment. In this position, the catheter steers freely and will not hold a preset curve. Rotating the Tension Control Wheel clockwise increases tension. In the "(+)" position, maximum tension is achieved. The catheter should not be steered in the maximum "(+)" position.
- 5) Connect the Automatic Personality Module (or APM) to the Cardiac Ablation Controller "Isolated Patient Connection" located on the front panel using the attached patient cable. Be sure to carefully follow the instructions in the Operator's Manual to connect the APM.
- 6) Connect the steerable ablation catheter to the APM by plugging the proximal pin leads at the end of the catheter (pin configuration) or at the end of the Quick Connect Instrument Cable (quick connect configuration) into the four standard female-pin connectors labeled "Distal 1,2,3,4 CATHETER". Thermistor steerable ablation catheters have three (3) additional pins marked "A, B, and C" which are attached to the color-coded thermistor connections labeled "A, B, C TIP TEMPERATURE" on the Automatic Personality Module (APM). Quick connect configuration catheters may be connected to the pin connect or quick connect APM through the use of various adaptor cables (reference Figures 2 and 3).
- 7) Once the ablation site has been accessed and the tip of the catheter is in contact against the endocardial surface, intracardiac electrogram signals may be obtained. Unipolar electrograms can be obtained between the distal tip electrode and any commercially available low impedance ECG electrode. Bipolar electrogram recordings can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes.

- 8) Once the arrhythmogenic site has been located, the same catheter can be used therapeutically in the "Ablate" mode to deliver discrete bursts of radiofrequency power. Radiofrequency power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue. To deliver radiofrequency power from the Cardiac Ablation Controller to the catheter, follow the instructions in the Cardiac Ablation Controller Operator's Manual.
- 9) If the physician knows that the tip is in a confined space or in a region of unusually low flow such as under a valve leaflet, a lower initial power set point (10-20 watts) should be used. Otherwise, start the ablation at an intermediate RF power level of 20-25 watts, which will facilitate subsequent upward or downward adjustments.

Catheter Removal

- 1) Prior to removing the catheter, ensure that the distal end of the catheter is straightened completely.
- 2) Withdraw the catheter from the vessel.
- 3) Remove the introducer sheath, then follow standard practice for management of the insertion site.

Electrophysiology Endpoints

Target sites are selected based on both the location of the ablation catheters on fluoroscopy and on the characteristics of the intracardiac electrogram recorded from the distal poles of the ablation catheter. The effectiveness of each radiofrequency power application is assessed by recording of the surface ECG, intracardiac signals and by incremental pacing and extrastimulation. These maneuvers provide objective evidence of whether conduction has been blocked in the targeted pathway and whether SVT remains inducible. Specific endpoints for each type of ablation are as follows:

Accessory Pathway - Successful ablation is defined as the complete elimination of conduction over the accessory pathway. This is evident as an abrupt increase in the AV and V-A intervals recorded at the target site. This is accompanied by a change in the retrograde activation sequence. In patients with manifest pre-excitations, successful ablation is associated with disappearance of the delta wave from the surface ECG. Patients with successful AP ablation no longer have inducible SVT mediated by the pathway.

AVNRT - There are two techniques for AV nodal modification in patients with typical AVNRT. Lesions made anteriorly, near the apex of the triangle of Koch, selectively affect fast AV nodal pathway functions. Endpoints for fast pathway ablations include an increase in the AH interval and an increase in the VA block cycle length by at least 50% over baseline.

Lesions made posteriorly, near the ostium of the coronary sinus interfere with slow AV nodal pathway function. Endpoints for slow pathway ablation include the occurrence of junctional ectopy during delivery of RF power as well as changes in AV nodal function. After successful slow pathway ablation, there is often elimination of dual AV nodal physiology. However, in some patients, there is attenuation without complete elimination of slow pathway function. These patients have discontinuous AV nodal function curves and sometimes have single AV nodal entrant echo beats after ablation. An endpoint which is sought in all patients after AV nodal modification is the elimination of inducible, sustained AVNRT.

AV Junction Ablation - The occurrence of persistent complete AV block after RF power applications is the endpoint for AV junctional ablation. Complete AV block is readily diagnosed by observation of the surface ECG and/or intracardiac electrograms.

Clinical Study Results

In clinical studies of the SteeroCath-T and SteeroCath-A in over 450 patients, the following ablation procedures were performed:

- **Accessory Pathway Ablation.** Candidates were patients with Wolff-Parkinson-White (WPW) Syndrome or concealed accessory pathways. Successful ablation of accessory pathways was curative.
- **AV Nodal Modification.** Candidates were patients with AV nodal reentrant tachycardias (AVNRT). Successful AV nodal modifications obviated the need for a pacemaker and was curative.
- **AV Junction Ablation.** Candidates were patients with atrial fibrillation or flutter. Successful ablation of the AV junction produced third degree atrioventricular (AV) block and necessitated insertion of a permanent ventricular pacemaker.

A total of 462 patients were enrolled in the study. Six patients were excluded from the analysis of efficacy, either because their arrhythmias could not be induced and they were not treated with the device (4 patients), or they did not meet the study inclusion criteria (2 patients).

An intention-to-treat analysis for evaluating effectiveness was based on the 456

patients who met the inclusion criteria. The outcome of the initial procedure was used in the calculation of success, and the use of non-protocol catheters during that initial procedure constituted a failure. Successful ablations were performed in 207 of 257 (81%) of patients with accessory pathways, 116 of 126 (92%) of patients with AVNRT, and 52 of 56 (93%) of patients with a rapid ventricular response to an atrial arrhythmia, for an overall success rate in patients with a single ablation indication of 85% (375/439). For the remaining 17 patients who had two indications for ablation, complete success was obtained in 9 patients (53%), and partial success, that is defined as one successfully ablated target, was observed in 3 patients (18%).

The outcomes from procedures in all 462 enrolled patients were included in the safety analysis, which included 42 repeat ablations after an initial failure or recurrence, and 9 additional ablation procedures in patients who were later identified as having a second ablation indication. A total of 57 complications were reported during these 513 procedures for a complication rate of 11%. Seventeen of the 57 complications were attributed to the ablation catheter.

Five deaths were reported among the patients during follow-up. Pulmonary embolism secondary to femoral vein thrombosis and endocarditis at the ablation site contributed to deaths that occurred within two months of the ablation procedure, in 2 of the 458 patients (0.44%).

The following were also noted:

- Clinical data indicated an overall recurrence rate of approximately 10% for patients undergoing successful ablation with the EPT Cardiac Ablation System. Most recurrences were noted in AV Modification procedures and recurrences were rarely noted following AV junction ablation.
- No data were collected to support that the thermistor ablation catheter is more safe and effective than the standard ablation catheter. Although a significant reduction in the incidence of impedance rise was observed during the study when the thermistor catheter was used because the operator could decrease power when measured temperature increased, no benefit to the patient was demonstrated.
- Typical anticoagulation protocols during left-sided procedures in the clinical study included: 1) an initial intravenous heparin injection of 3,000-10,000 units, 2) maintenance of appropriate heparinization by heparin drip or repeat bolus if necessary; followed by 3) post procedural administration of one aspirin per day for a period of one to three months unless contraindicated.
- The average fluoroscopy time was 39.9 ± 29.9 minutes and ranged from a minimum of 5 minutes to a maximum of 157 minutes.

Table A summarizes power delivery and temperature data from the study for the three different types of ablation procedures performed in the clinical trials.

Table A: Summary of Power Delivery for Accessory Pathway, AV Modification and AV Junctional Ablation Procedures

	Number of RF Applications >10 Seconds	Applied Power (Watts)	Duration (Seconds)
AV Junction : Ablation	Range: 1-14 Median: 3	Range: 14-50 Median: 31.5	Range: 11-120 Median: 41.9
Total (N=52)			
AV Modification:	Range: 1-44 Median: 5	Range: 5-50 Mean: 29.3	Range: 11-120 Mean: 32.3
Total (N=115)			
Accessory Pathway:	Range: 1-34 Median: 3	Range: 3-50 Mean: 33.2	Range: 11-111 Mean: 29.3
Total (N=207)			

Although no specific protocol was designed to evaluate the use of thermometry, there were no differences observed in safety and effectiveness of the device with or without the thermistor. The following observations were noted:

- Insufficient tissue heating was occasionally associated with either a lack of, or non-permanent interruption of conduction at the target site. Conversely, high temperatures increased the likelihood of an impedance rise due to coagulum formation on the electrode tip.
- During successful ablations, temperature rose steadily before leveling off at a constant temperature plateau. Operators tended to reduce RF power levels when the measured temperature showed no sign of leveling off as it approached a desired target temperature level. When RF power was not reduced in the presence of an excessively rapid temperature rise, the temperature would typically exceed the targeted temperature.

- When temperature did not increase upon the delivery of RF power, or when the temperature was rather low and irregular, operators typically suspected the catheter tip-to-endocardium contact was unstable. Similarly, sudden temperature drops observed during ablation were interpreted as indicating loss of tissue contact, or a shifted tip position. When these temperature patterns were observed, ablation was stopped, and the catheter was repositioned to improve tip-tissue stability and ensure the intended site was being accessed. RF power delivery was then resumed after repositioning, to avoid ineffective power delivery and/or ablation of unintended regions.

Limited Warranties

Boston Scientific/EP Technologies™ warrants that its products are free from defects in original workmanship and materials. EPT warrants that sterile products will remain sterile for a period of two years as labeled as long as the original packaging remains intact. EPT's products are designed for single use, only. EPT's products are not designed for reuse. If any EPT product is proved to be defective in original workmanship or original materials, EPT, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products which have been used for their normal and intended uses. EPT's limited warranty shall NOT apply to EPT product which have been resterilized, repaired, altered, or modified in any way and shall NOT apply to EPT products which have been improperly stored or improperly installed, operated or maintained contrary to EPT's instructions.

DISCLAIMER AND EXCLUSION OF OTHER WARRANTIES

There are no warranties of any kind which extend beyond the description of the warranties above. EPT disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use or purpose.

LIMITATION OF LIABILITY FOR DAMAGES

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that EPT shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. EPT's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by EPT to buyer which give rise to the claim for liability.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

5195968; 5230349; 5254088; 5257451; 5257635; 5336182; 5363861; 5364351; 5363874; 5273535; 5358478; 5395327; 5456682; 4566682; 5531686; 5524337; 5309910; 5313943; 5398683; 5471982; 5549108; 5489275; 532846. Other U. S. Patents pending; foreign counterparts also pending.

Table B
Technical Specifications

Features	Dimension Range—
Torque Attributes	
Standard	SteeroCath
High Torque	Blazer II
Handle Style	Dual Lever
Catheter Length	60 - 130 cm
Catheter Shaft Diameter	6 or 7 F
Distal-End	
Length	6.6 - 15 cm
Stiffness	Soft (SteeroCath or Blazer II) Firm (Blazer II only)
Tip Electrode	Tip Diameter / Length
For 6F Catheters	6F / 4mm 7F / 4mm
For 7F Catheters	7F / 4mm 8F / 4mm 8F / 5mm
Curve Configurations	
Symmetric	Standard, K1, K2
Asymmetric	N1, NR1, N2, N3, N4, N5,
Electrode Configuration	
Tip-to-First-Ring	2.5mm
Ring-to-Ring	1-10mm
Ring Electrode Width	1.25mm
Electrode Configuration	
Bipolar	2 Electrodes
Quadrupolar	4 Electrodes
Electrical Connector	Quick Connect Pin Connect